

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION**

DENISE HUGHES,

Plaintiff,

v.

COLOPLAST CORP. et al.,

Defendants.

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Civil Action No. 4:19-cv-00299-P

MEMORANDUM OPINION AND ORDER

Before the Court is Defendant Coloplast A/S's Motion to Dismiss (ECF No. 31), Plaintiff Denise Hughes's ("Hughes") Response (ECF No. 33), and Coloplast A/S's Reply (ECF No. 35). Having considered the Motion to Dismiss, related briefing, and applicable law, the Court finds that Coloplast A/S's Motion to Dismiss should be and is hereby **DENIED**.¹

BACKGROUND

Hughes alleges personal injuries arising out of damages she sustained from a pelvic mesh device called "Exair" that was implanted in her body in a procedure performed in the State of Texas. *See* MTD Resp. Hughes claims that the product implanted in her body was

¹Coloplast A/S had filed a 12(b)(2) and 12(b)(6) motion to dismiss prior to Hughes filing her First Amended Complaint. Thus, given the filing of the First Amended Complaint, Coloplast A/S's initial Motion to Dismiss (ECF No. 21) is hereby **DENIED as moot**. *See Garza-Selcer v. 1600 Pac. Subtenant, LLC*, No. 3:15-CV-03791-N, 2016 WL 11474103, at *2 (N.D. Tex. Aug. 30, 2016) ("When a motion to dismiss is filed against a superseded complaint, courts ordinarily deny the motion as moot.").

defectively designed and that Defendants Coloplast Corp.; Coloplast A/S; and Coloplast Manufacturing, US, LLC failed to adequately warn Plaintiff's treating physician of the risk attendant to the product's use. *Id.*

Hughes filed the underlying civil action on April 9, 2019. ECF No. 1. On October 13, 2019, Hughes filed her First Amended Complaint in which she alleges that Defendants: (1) were negligent in the design, manufacture, testing, inspection, processing, advertising, marketing, testing, labeling, assembling, packaging, distribution, warning, detailing, promotion and sale of its Exair brand mesh device; (2) negligently misrepresented that the product had been adequately tested and found to be safe and effective for the treatment of female pelvic organ prolapse; and (3) were grossly negligent by showing a complete indifference for the safety and health of Plaintiff and others similarly situated in negligently designing, packaging, labeling, marketing, advertising, promoting, distributing and selling a defective and unreasonably dangerous product. *See* ECF No. 27.

Coloplast A/S filed a Motion to Dismiss ("MTD") pursuant to Federal Rule of Civil Procedure 12(b)(2), claiming a lack of personal jurisdiction on the basis that Coloplast A/S is a foreign corporation incorporated and operating in Copenhagen, Denmark, and that there were insufficient contacts within Texas for this Court to have personal jurisdiction over Coloplast A/S. *See* MTD at 2. Coloplast A/S claims it does not have any offices in the United States, and it maintains its business records exclusively in Denmark. *Id.* Coloplast A/S further contends that the Interventional Urology ("IU") business unit of Coloplast Corp., a subsidiary of Coloplast A/S, is responsible for the testing development, regulatory

clearance, distribution, marketing, and sale of Coloplast Surgical Mesh Implants in North America, including the Exair surgical mesh that was implanted in Hughes. *Id.*

Coloplast Corp. is a Delaware corporation with a principal place of business in Minneapolis, Minnesota. *Id.* Coloplast A/S contends that all corporate formalities are observed between it and its subsidiary Coloplast Corp., that Coloplast Corp. maintains separate profits and losses from any other Coloplast entity, maintains its own books and records, and has the right to hire and fire its own employees. *Id.* Lastly, Coloplast A/S stresses that the IU business unit does not have any employees from Coloplast A/S, and further, that no employee of the IU unit involved in product development, distribution, marketing, clinical, regulatory affairs, or sales in North America reports to any employee of Coloplast A/S. *Id.*

Hughes filed her Response to this Motion to Dismiss on November 29, 2019, (ECF No. 33), and Coloplast A/S filed its Reply on December 13, 2019 (ECF No. 35). This Motion is now ripe for review.

LEGAL STANDARDS

A. Federal Rule of Civil Procedure 12(b)(2)

“When a nonresident defendant presents a motion to dismiss for lack of personal jurisdiction, the plaintiff bears the burden of establishing that in personam jurisdiction exists.” *Stuart v. Spademan*, 772 F.2d 1185, 1192 (5th Cir. 1985); *D.J. Invs., Inc. v. Metzeler Motorcycle Tire Agent Gregg. Inc.*, 754 F.2d 542, 545–46 (5th Cir. 1985). The plaintiff need not, however, establish personal jurisdiction by a preponderance of the evidence; prima facie evidence of personal jurisdiction is sufficient. *Wyatt v. Kaplan*, 686

F.2d 276, 280 (5th Cir. 1982). The court may resolve a jurisdictional issue by reviewing pleadings, affidavits, interrogatories, depositions, oral testimony, exhibits, any part of the record, and any combination thereof. *Stuart*, 772 F.2d at 1192. Allegations in the plaintiff's complaint are taken as true except to the extent that they are contradicted by defendant's affidavits. *Wyatt*, 686 F.2d at 282–83 n.13 (citing *Black v. Acme Markets, Inc.*, 564 F.2d 681, 683 n.3 (5th Cir. 1977)). Any genuine, material conflicts between the facts established by the parties' affidavits and other evidence are resolved in favor of plaintiff for purposes of determining whether a prima facie case exists. *Bullion v. Gillespie*, 895 F.2d 213, 217 (5th Cir. 1990).

B. Personal Jurisdiction

In a diversity action, a federal district court may exercise personal jurisdiction over a nonresident if (1) the nonresident defendant is amenable to service of process under the law of a forum state, or (2) the exercise of jurisdiction under state law comports with the due process clause of the Fourteenth Amendment. *Stuart*, 772 F.2d at 1189 (internal citations omitted). Since the Texas long-arm statute has been interpreted as extending to the limits of due process,² the only inquiry is whether the exercise of jurisdiction over the nonresident defendant would be consistent with due process. *Id.*

The exercise of jurisdiction over a nonresident defendant comports with due process if (1) the nonresident defendant has purposefully availed himself of the benefits and protections of the forum state by establishing minimum contacts with the forum state; and

²See, e.g., *Kawasaki Steel Corp. v. Middleton*, 699 S.W.2d 199, 200 (Tex. 1985).

(2) the exercise of jurisdiction over the defendant does not offend “traditional notions of fair play and substantial justice.” *Latshaw v. Johnston*, 167 F.3d 208, 211 (5th Cir. 1999) (quoting *Int’l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)). A defendant’s contacts with the forum state constitute minimum contacts if they are such that he “should reasonably anticipate being haled into court there.” *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980).

Minimum contacts may give rise to general or specific jurisdiction.³ *Luv N’ Care, Ltd. v. Insta-Mix, Inc.*, 438 F.3d 465, 469 (5th Cir. 2006). For specific jurisdiction to exist, the foreign defendant must purposefully do some act or consummate some transaction in the forum state and the cause of action must arise from or be connected with such act or transaction. *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 475 (1985). “The appropriate inquiry is whether the defendant purposefully availed [itself] of the privilege of conducting activities in-state, thereby invoking the benefits and protections of the forum state’s laws. *Id.* at 474–75.

The plaintiff “bears the burden of establishing jurisdiction but is required to present only *prima facie* evidence.” *Pervasive Software Inc. v. Lexware GmbH & Co. KG*, 688 F.3d 214, 219 (5th Cir. 2012). When a plaintiff establishes minimum contacts between the defendant and the forum state, the burden of proof shifts to the defendant to show that the exercise of jurisdiction would not comply with “fair play” and “substantial justice.” *Freudensprung v. Offshore Tech. Servs., Inc.*, 379 F.3d 327, 343 (5th Cir. 2004).

³Because Hughes does not allege general jurisdiction, the Court focuses its analysis on whether Hughes has established that the Court has specific jurisdiction over Coloplast A/S.

When a nonresident defendant commits a tort within the state, or an act outside the state that causes tortious injury within the state, that tortious conduct amounts to sufficient minimum contacts with the state by the defendant to constitutionally permit courts within that state, including federal courts, to exercise personal adjudicative jurisdiction over the tortfeasor and the causes of actions arising from its offenses or quasi-offenses.

Guidry v. U.S. Tobacco Co., 188 F.3d 619, 628 (5th Cir. 1999). Further, the stream of commerce doctrine “recognizes that a defendant may purposely avail itself of the protection of a state’s laws—and thereby will subject itself to personal jurisdiction—by sending its goods rather than its agents into the forum.” *In re DePuy Orthopaedics, Inc.*, 888 F.3d 753, 778 (5th Cir. 2018). Indeed, “a nonmanufacturing parent will sometimes lie within the stream (even where the corporate veil remains intact).” *Id.* at 779.

Accordingly, for Coloplast A/S to be subject to specific jurisdiction, Hughes must show that it had sufficient minimum contacts within Texas or that it delivered the product that injured her “into the stream of commerce with the expectation that it would be purchased by or used by consumers in the forum state.” *Ainsworth v. Moffett Eng’g, Ltd.*, 716 F.3d 174, 177 (5th Cir. 2013). The Court in *In re Depuy* considered the following factors to determine whether a nonmanufacturing parent lies within the stream of commerce: (1) the parent’s control over product advertisements and patient brochures, (2) representations the parent company made to regulatory bodies, (3) the parent’s funding for promotional activities and referring to the product as its own, (4) the parent granting the subsidiary clearance to use and sell the product, (5) the parent placing its logo on the packaging that was ultimately received in the forum State, and (6) the parent has consulted with doctors in the forum state. 888 F.3d at 779–80.

ANALYSIS

A. Coloplast A/S Controlled Advertisements and Patient Brochures

In a separate lawsuit, a Coloplast Corp. employee in its marketing department testified that Steffen Hovard—the Vice President of Business Development at Coloplast A/S—was responsible for “driving the strategy that led us into urology.” *See* MTD Resp. Ex. 9, Trial Transcript at 605. The employee also testified that if he attempted to start a project or initiate “a certain marketing message,” Hovard, in Denmark, had to approve it. *See* Ex. 10, Depo. at 82–83. Hughes alleges that Coloplast Corp.’s marketing message—which the evidence shows was at the very least approved by Coloplast A/S—found its way to Texas and into the hands of the physician who implanted the Exair into Hughes. *See* Amended Compl. at ¶ 88. Hughes’s allegations are not contradicted by Coloplast A/S’s evidence. The Court **FINDS** that this evidence weighs in favor of the contention that Coloplast A/S placed the Exair into Texas’s stream of commerce.

B. Coloplast A/S Made Representations to Regulatory Bodies

Another factor considered by the Fifth Circuit in *Deputy* are representations made by a parent company to regulatory bodies. 888 F.3d at 779–80. Attached to Hughes’s Amended Complaint is a 510(k) premarket notification for the Exair submitted to the Food and Drug Administration (“FDA”) by Coloplast A/S. *See* Ex. 4. This notification reads “Coloplast A/S hereby submits this Traditional Premarket Notification 510(k) in duplicate to request clearance for the Exair Anterior and Posterior Prolapse Repair Systems.” The Court **FINDS** that Coloplast A/S’s submission of a premarket notification to the FDA for

the Exair also weighs in favor of Coloplast A/S putting the Exair into Texas's stream of commerce.

C. Coloplast A/S Approved the Design and Granted Coloplast Corp. Clearance to Use and Sell the Exair

Coloplast Corp. emails attached to Hughes's Amended Complaint show that Coloplast A/S approved the design of the Exair. *See* Ex. 6. In one email, Coloplast Corp. employee Julie Woessner wrote "as a follow up to one of the observations from the Exair audit, Sarah was able to find the meeting minutes issued by Denmark, (signed by Steffen Hovard), indicating approval of Gate 1 for Shaped Mesh." *Id.* Therefore, Steffen Hovard, a Coloplast A/S employee, was responsible for approving the design of the Exair.

Moreover, during the deposition of a different Coloplast Corp. employee, the employee testified that she had reported to her boss Elsebeth Aagaard—a Coloplast A/S employee in Denmark—regarding the clinical testing of the Exair. *See* Ex. 8.

The Court **FINDS** that Coloplast A/S's involvement in the design of, and subsequent approval for Coloplast Corp. to sell the Exair weighs in favor of Coloplast A/S putting the Exair into Texas's stream of commerce and thus subjecting itself to this Court's jurisdiction.

D. Coloplast A/S Placed its Logo on Hughes's Surgical Mesh Package

In its Motion to Dismiss, Coloplast A/S contends that it "does not manufacture and did not design the Exair surgical mesh implant at issue in this case." Def.'s Mot. Dismiss at 2. However, the Specific Instructions for Use ("IFU") that were sent to Hughes's implanting physician in Texas contain the Coloplast logo which is "a registered trademark

of Coloplast A/S.” *See* MTD Resp. Ex. 2. Furthermore, in the bottom right corner of the IFU, Coloplast A/S is labeled as the “Manufacturer” of the Exair. *Id.* This directly contradicts Coloplast A/S’s declaration that it is not the manufacturer of the product that was sold to Hughes. As the Fifth Circuit explained in *Bullion*, factual disputes at this stage of litigation must be resolved in favor of the plaintiff. 895 F.2d 213, 217.

The Court **FINDS** that this evidence weighs in favor of the contention that Coloplast A/S placed the Exair into Texas’s stream of commerce and therefore is subject to this Court’s jurisdiction.

E. Coloplast A/S Targeted and Consulted with Doctors in Texas

Hughes contends that “Coloplast A/S, thru [sic] its employees, intentionally decided to market and distribute the Exair device in the State of Texas.” *See* Amended Compl. at ¶ 84. Coloplast A/S has not contested these allegations, and as already noted, factual allegations at this stage of litigation must be resolved in favor of the plaintiff.

Hughes avers that Coloplast A/S “established the strategy for hiring key opinion leaders” (“KOL”), who were doctors in Texas in order to educate other Texas doctors about Coloplast A/S products. Coloplast A/S and its agents organized sales events and hired KOL doctors in Texas. *See* Amended Compl. at ¶ 93. Coloplast A/S does not dispute this allegation. In fact, internal emails confirm that Coloplast A/S employees dictated the “KOL” strategy for surgical urology worldwide and directed the sales force in the United States to target doctors in order to “[m]aximize awareness of the existing Coloplast WH products.” *See* Ex. 11. Thus, it is uncontroverted that the “KOL” strategy established by

Coloplast A/S in Denmark was targeted at Texas and, more specifically, Hughes's implanting doctor, Dr. Cannon-Smith.

As outlined in the Amended Complaint, on September 30, 2014, Mrs. Hughes was implanted with the Exair device at the USMD Hospital in Arlington, Texas by her physician, Dr. Tracy Cannon-Smith. *See* Exhibit 12. An email from Julie Kerkvliet—a Texas employee of Coloplast Corp. in the Female Pelvic Health Marketing Division—shows that prior to implanting the Exair in Mrs. Hughes, Dr. Cannon-Smith was targeted as a potential “KOL” for Coloplast. On February 9, 2010, Kerkvliet wrote “I wanted to share a huge success with you from Ryan’s territory! Dr. Tracy Cannon-Smith (#8 on Ryan’s BEST list) just completed her first Exair case.” *See* Exhibit “13”. A reply to Kerkvliet’s email noted that Dr. Cannon-Smith was a “very good physician” that has “a great attitude” and who will be “very pleasant on the podium at major meetings.” *Id.* Several years later, Dr. Cannon-Smith agreed to be paid as a “regional consultant,” “proctor” and “trainer for Coloplast.” *See* Ex. 14.

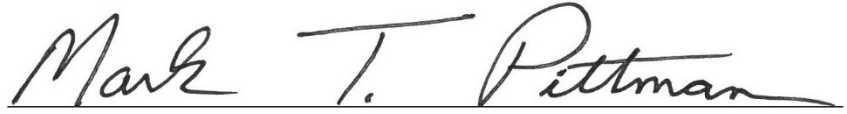
As the KOL strategy was devised in Denmark, by Coloplast A/S, the Court **FINDS** that this evidence weighs in favor of the contention that Coloplast A/S placed the Exair into Texas’s stream of commerce and therefore is subject to this Court’s jurisdiction.

CONCLUSION

Based on the foregoing, the Court hereby **HOLDS** that Coloplast A/S has sufficient minimum contacts with the state of Texas, and therefore is subject to personal jurisdiction

in this Court. As a result, the Court concludes that Coloplast A/S's Motion to Dismiss (ECF No. 31) should be and is hereby **DENIED**.⁴

SO ORDERED on this **8th day of June, 2020**.

A handwritten signature in black ink, reading "Mark T. Pittman". The signature is written in a cursive, flowing style. The first name "Mark" is written with a large, stylized 'M'. The middle initial "T." is written with a simple 'T' followed by a period. The last name "Pittman" is written with a large, stylized 'P' and a trailing flourish.

Mark T. Pittman
UNITED STATES DISTRICT JUDGE

⁴Because the Court concludes that it has specific jurisdiction over Coloplast A/S through the stream of commerce analysis, the Court need not address Hughes's argument that personal jurisdiction exists via an alter ego theory.